

EXHIBIT 191

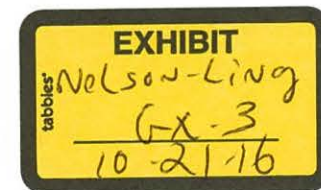


2008 Audit of Sales Representatives Interactions With Healthcare Professionals

Natasha Nelson- Executive Director

David Hollasch – Director Regulatory Compliance

March 25, 2009



Issues related to Monitoring the Speaker's Performance at Programs

- Lack of guidance/criteria provided to representatives in monitoring the speaker's performance.
 - Event Alliance Program close out question for representatives – Did the Speaker follow Novartis Policies?
 - Representatives are not provided a copy of the slide deck for use
 - At EXCEL programs, NPC rep responsibility is unclear as no speaker evaluation is required
- Of the 36 AHM programs we attended, issues were noted with the speaker on 10 programs. For all 10 programs, the Lead Representative indicated the speaker followed NPC policies.
- Upon inquiry with AHM, we noted 791 representatives indicated from 1/1/08 to 3/11/09 that speakers had violated NPC Policy. These policy violations were not being followed-up on.

Speaker Performance and/or Conduct Issues

We attended 36 AHM and 9 Nelson Group Programs, and observed:

- 20 speakers did not disclose they are receiving financial support by NPC
- One speaker provided two handouts to the audience - a pamphlet for ISCD (Int'l Society of Clinical Densitometry) and a link to a web-based tool from the University of Sheffield (created by WHO)
- One speaker (affiliated with Thomas Jefferson University) introduced an HCP attendee who presented data from Thomas Jefferson University Hospital. The HCP stated that Jefferson was the only local transplant center that performed statistically significantly better than the national average, emphasizing that outcomes are very, very good.
- The speaker and one other program attendee telling slightly off-colored jokes prior to the start of the event

Speaker Performance Issues - Presentation of Slide Deck

- Additional observations from our 45 programs:
 - Many speakers did not use the slide decks provided
 - 8 speakers skipped slides, mostly on safety and fair balance
 - 3 speakers added slides – covering kidney transplants & survival rates; transition slides due to deletions; and slides tailored to black patient populations
 - Less than 10-15 minutes total time for many CV presentations
- Speaker comments on approved slides:
 - After presenting dosage information, speaker proactively indicated his practice preferred a higher dosage even though the product had no indication at that dosage
 - Speaker stated "add Tekturna to ACE, get 40% improvement in efficacy", claiming that this was "missing" from the slide
 - Speaker stated that Tyzeka slide is misleading – n's are different. Tyzeka "is worse than Lamuvidine"

Speaker Performance Issues – Inappropriate Speaker Comments

- We noted many inappropriate comments at our 45 programs, including:
 - One speaker explained that the correct way to use a inhaler was “To suck on it like using a bong”.
 - One speaker who frequently referred to articles in the New England Journal of Medicine and other clinical studies not mentioned on the slide deck.
 - After presenting safety information one speaker added “None of us will probably see it [atrial fib] since numbers are so low... About the probability of a shark attack or winning the lottery”
 - One speaker who said in a side conversation to 2-3 people that he uses Namenda on all patients in conjunction with the Exelon Patch.
 - At a Focalin program, the speaker asked the audience if they have ever used more than 20mg dose, mentioning this was off-label. 2 HCPs stated they had never used more than 20mg, 1 HCP stated that used 20mg twice a day for a patient that had a higher metabolism. Speaker then brought it back to on-label discussion.

Speaker's Performance Issues – Recommended Corrective Action

■ Recommended Corrective Action

- Develop a checklist for the Lead Representative to use as guide for reviewing all aspects of the speaker's performance for compliance with NPC Policies
- Provide representatives a copy of the program presentation to use in monitoring the speaker's performance
- Implement process assigning responsibility for follow-up on sales representative's "No" reply when evaluating the speaker's performance
- Review speaker training sessions to ensure conduct and performance issues are adequately addressed, and revise accordingly
- Revise speaker contracts to include clauses that address speaker non-compliance with NPC Policies, including potential contract termination

Attendance Issues at Programs

- We audited 36 AHM programs and 9 EXCEL programs, noting:
 - 3 had an insufficient number of HCP attendees (<3) to qualify as a valid program
 - 12 (33%) of the AHM programs indicated an inaccurate number of attendees. Actual attendees were understated on 9 programs and overstated on 3.
 - Understatement hides non-legitimate attendees (spouses, friends)
 - Overstatement reduces the per person meal cost and can hide policy violations including the \$125 meal limit per person and minimum 3 HCP attendee requirement
 - Under and Over statements result in incorrect allocation of meal costs to HCPs
 - 17 (47%) of the AHM programs and 27 (93%) of the EXCEL programs failed to capture complete HCP information on the Sign in Sheet, missing data on the HCP's degree, specialty, and/or address
 - We observed several attendees that did not appear to be legitimate
 - Incomplete HCP data may prevent proper allocation of costs and inaccurate reporting of HCP spend
 - Incomplete attendee data hides unauthorized attendees

Attendance Issues at Programs (continued)

- 7 (19%) programs where apparent non-HCP relatives of the speaker or another participating physician attended¹⁹
- 7 EXCEL programs with attendee specialties from one or more non-cardiovascular arenas, including **Anesthesiologists, Oncology or “Onc”, Pediatrics or “Ped”, OB/GYN, Med Psych and “Ger”**
- For 19 of the 29 EXCEL programs, the Novartis reps/home office personnel did not sign-in
- No FLM review and approval of representative’s programs. Removal of the FLM requirement to review representative’s programs when AHM took over as the speaker bureau has led to many of the issues raised in this report
- Unclear what NPC Representative responsibility is at Nelson Group EXCEL programs

Event Alliance Data Integrity Issues

- Event Alliance HCP degree data codes do not match the Novartis HCP Degree Matrix codes
- The Event Alliance “Degree” field is populated with “specialty” codes such as IM, SURG, URO, etc.
- Data populated into the Degree and Specialty fields was the same for the 36 programs reviewed. These fields must be accurate, as they are critical drivers for
 - Compliance reporting – accurate cost per HCP and non-HCP
 - Event planning and monitoring – for example, correct fields would prevent inviting an anesthesiologist to a Diovan program
 - Monitoring for abuse – detect HCP and non-HCP attendees with same surname – for example MD attending a program with their spouse

Program Attendance and Data Integrity Issues

- Unclear Representative responsibility for:
 - Performing a final count of attendees physically present and comparing it to the number of attendees signed in – ensuring all attendees are accounted for
 - Ensuring that all attendees are appropriate HCPs i.e. correct specialty.
 - Ensuring that spouses and other relatives are not present unless a legitimate attendee in their own right
 - Submitting copies of attendee sheets and verifying accuracy of their data input to Event Alliance records
- Recommended Corrective Action:
 - Reinforce responsibility of the sales representatives and sales management for obtaining accurate Sign In Sheet data by incorporating it into the annual performance objectives.
 - Reinforce sales representative's responsibility for assuring that only legitimate target attendees are permitted attendance to programs and all inappropriate guests are turned away. Develop and provide tools to representatives to handle attendance issues at programs.

Program Attendance and Data Integrity Issues

- Recommended Corrective Action (continued):
 - Require FLMs to review Event Alliance records for compliance with NPC Policies
 - Implement a procedure where the representative must perform a physical count of attendees, compare that total to the number of attendees per the attendee sign in sheet, and resolve any differences noted.
 - Enhance exception reporting process with periodic escalation up to the General Manager and Business Practices Office for all FMPSEs for which the sales representative failed to submit the attendee sign in sheet.
 - Align the Event Alliance HCP codes with the Novartis HCP Degree Matrix and assign responsibility to periodically review records for agreement

Meal Cost Issues at Programs

- Representatives claim no fiscal responsibility for review of itemized receipt for accuracy of all charges, including excessive meals and alcohol (“wine decanted”), and items “To Go”
- 11 programs exceeded the \$125 meal cost per attendee limit.
 - 6 AHM programs, 3 highest meal averages: \$196.98; \$137.24 and \$134.41
 - 5 EXCEL programs, 3 highest meal averages: \$192.15; \$190.36 and \$186.17 3
- 12 programs (3 AHM, 9 EXCEL) with excessive charges for alcoholic beverages. Excessive is defined by audit as > 20% of the pre tax & tip total cost:
 - AHM - \$1,653 or \$53 per attendee, 33%. Charged for 27 bottles of wine for 31 attendees.
 - EXCEL - \$3,326 or \$59 per attendee, 32%. Charged for 41 bottles of wine and 71 bar drinks for 56 attendees.
- 5 programs (2 AHM, 3 EXCEL) where meal charges were not supported by an itemized receipt – only a summary by category.

Meal Cost Issues at Programs (continued)

- 8 programs with apparent overcharges, including:
 - Charges for more meals than program attendees
 - Calculated as a physical count of attendees vs. itemized receipt
 - NPC charged for a collective total of 42 additional meals
- The overcharges totaled \$4,484 or \$560 per each of 8 programs:
 - Example: Program with 10 attendees, charged for 12 meals @ \$70 each. Room charge of \$456.75 assessed to bring subtotal to \$1,400 – minimum spend?
 - The auditor at this program observed a waiter inform the representative that a balance remained and if they wanted to order entrees and desserts to go. The representative declined.
 - Example: Program with 8 attendees, charged for 10 meals @ \$80.95 each.
 - Additional \$80 service charge also assessed – apparently in order to “meet” \$1,000 minimum spend.

Meal Costs Issues at Programs (continued)

- Minimum guarantees causing “wasted” money:
 - On 3 of these programs (8%), apparent minimum guarantee expenditures at the venue were met by assessing additional meals and room rental charges or other fees
 - Reps complained that AHM did not “ask” them or “advise” them of minimum guarantees on food or room charges
 - Reps said that venues could have been changed to avoid minimums
 - Event Alliance has no apparent field available to NPC end users to indicate which programs had a minimum guarantee
- Insensitivity in Diversity & Inclusion Issues:
 - Inappropriate food at one luncheon speaker program, as chicken rigatoni was entrée ordered for an audience that consisted primarily of vegetarians
 - During Ramadan, Muslim attendees had no accommodation for fact that they couldn’t eat until after a given time

Venue Issues at Programs Attended

- We audited 36 FMPSEs and 9 EXCEL speaker programs, noting:
- 5 (10%) events where loud background music, noise and restaurant staff traffic continuously interrupted the speaker and medical discussion
- 2 (4%) events where the NPC slides were visible to non-program venue customers and the discussion was not private.
- 2 (4%) events where slides were not presented on a large screen.
- Recommended Corrective Action
 - Add to the Event Alliance program close out evaluation an option enabling the Lead Representatives to prohibit future use of the venue.

Ride Along Findings

- Lack of a clear Sales Call Policy led to recording of calls without face to face discussions and other issues including:
 - 62% of calls contained a presentation of fair balance; 38% did not
 - Representative call logs frequently have entries with no data in several key fields including the HCP's first and last name, and specialty
- Melding of multiple product information into one sentence
 - Representatives talked about Diovan and Diovan HCT simultaneously thus making it unclear to the practitioner that Diovan HCT is not indicated for the treatment of heart failure and post-myocardial infarction
- Inappropriate marketing messages such as unapproved comparisons to competitor products, and statements regarding the efficacy and safety of NPC products
- Representatives that failed to recognize and report a patient who experienced an Adverse Event while taking an NPC product

Ride Along Findings (continued)

- In-Office meals that violated NPC policies
 - Dine n dash
 - Not present for medically relevant discussion
 - Fed attendees without attempt at medically relevant discussion
- Samples
 - Inventory management (rotation of NPC samples to move short dated samples to the front)
 - Representative inconsistency in sampling practices regarding review of practitioner sample bins for expired and/or short dated product
- Inappropriate representative behavior regarding the provision of gifts to HCPs and a patient
- A formal policy requiring District Manager review of a Sales Representative's call log did not exist

Recommended Corrective Action for Ride Along Findings

- Issue a Sales Call Policy
- Implement a revised Field Contact Report (FCR) with compliance prompts for the District Manager to use in evaluating the sales representative's compliance with delivering marketing messages, reporting adverse events, sampling licensed practitioners, holding and reporting modest meals, and all other NPC Policies involving interactions with HCPs.
- Assign responsibility to the District Managers for reviewing a sample on a monthly basis of sales representative call logs for agreement with In-Office HCP meal expenditures, representative target plans and completeness of HCP data.